REMARKS/ARGUMENTS

Claims 1 - 16 are pending in the application.

CLAIM REJECTIONS – 35 USC §112

The Examiner has stated that the term "non-implanted" as recited in claims 1 and 16 is indefinite. Applicants respectfully disagree, and offer the following comments and information in order to demonstrate that "non-implanted" is precisely the appropriate and proper term pursuant to FDA guidelines and requirements. The submitted information will furthermore demonstrate that the term "non-implanted" is the term of the art in the pertinent field, and is therefore definite, requires no definition since it is the term prescribed by the FDA, and is thus recognized by those in the industry to have specific metes and bounds. It is furthermore submitted that where a government agency requires a certain terminology, and defines such terminology, then it is this prescribed terminology that is binding (and actually required) and not an arbitrary dictionary definition.

In particular, reference will now be made to information from the database of the US Food and Drug Administration under Title 21 of the Code of Federal Regulations (see Exhibit 1).

As stated on page 1-1 of Exhibit 2, the FDA regulates devices to assure their safety and effectiveness. This is particularly true of medical devices. That the device of the present application clearly falls under the definition of a medical device can be seen from the paragraph on page 1-1 entitled **What is a Medical Device.** This is further confirmed by the approval letter received by Applicants from the FDA (see Exhibit 3), where Applicants' device is classified in regulatory class II, which is

further defined on page 1-2 of Exhibit 2. Applicants' FDA approval letter characterizes the device/system covered by Applicants' claims as a "non-implanted electrical continence device" pursuant to regulation number 876.5320. This regulation name and regulation number can be found in subpart F in Exhibit 4. The Examiner's attention is also directed to the definition of identification provided for a non-implanted electrical continence device as provided in Exhibit 5. The FDA provides a separate characterization for implanted devices of this type (see Exhibit 4, § 876.5270).

In view of the foregoing, Applicants respectfully submit that the term "non-implanted" is a term of art and in fact is the terminology prescribed by the FDA. Applicants there respectfully request that the objection for indefiniteness be withdrawn.

ALLOWABLE AND ALLOWED CLAIMS

The Examiner is thanked for the indication that claims 8 – 10 would be allowable, and that claims 14 and 15 are allowed. However, in view of the following comments, it is respectfully submitted that all of pending claims 1 – 16 are allowable.

REJECTION OF CLAIM 1 UNDER 35USC§102

The Examiner has rejected, among others, claim 1 as being anticipated by Guice.

MPEP Section 2131 indicates that **TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM.** This section indicates that "a claim is anticipated only if each and every element as set forth in the claim if found, either expressly or inherently described, in a single prior art

reference". Equally important is the further statement that "the identical invention must be shown in as complete detail as is contained in the ..... claim".

Applicants' claim 1, among other features, requires that the system is for humans, and is "adapted to be self-applied by a human" (emphasis added). This limitation of the combination probe, transceiver and power source, as well as the limitation to humans, are critical to defining the system of claim 1, and are entirely proper, as clearly set forth in MPEP Section 2173.05(g), which states in the first paragraph that "there is nothing inherently wrong with defining some part of an invention in functional terms". The beginning of the second paragraph of this MPEP section states that "a functional limitation must be evaluated and considered, just like any other limitation of the claim" (emphasis added).

The Guice reference, which the inventors incontrovertibly limit to animals, does not meet the foregoing limitation of claim 1, and therefore cannot teach or suggest Applicants' claim 1. It is furthermore respectively submitted that Guice also would not be considered by one of ordinary skill in the art, as attested to by the attached declarations (which have been slightly modified from those submitted on November 30, 2004). These declarations are directed, among other things, to the fact that the present application is for use in humans, and that the Guice reference, which is limited to use in animals, would be entirely inappropriate. Thus, the declarations are directed to a limitation of the claims, and are entirely proper for such use. It is respectively submitted that the Examiner has misapplied MPEP Section 716, which is directed to declarations used to support secondary evidence. This is not the case in the present application. Please note that the FDA regulation referred to in Dr. Jayne's declaration is attached as Exhibit 6.

With regard to the Examiner's use of language from the form paragraph in MPEP Section 707.07(f) concerning "intended use", the Examiner's attention is respectfully directed to the last paragraph of MPEP Section 2115, in which the In re Casey and In re Otto cases are cited. This MPEP paragraph states that "this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use. It does not apply to product claims or kit claims".

As further support for Applicants' argument that Guice is not applicable as a reference against a system where a combination probe, transceiver and power source is adapted to be self-applied by a human subject into the human vagina, it should be noted that the FDA clearly distinguishes between humans and animals. For example, reference is made to 21CFR895.1(d), which can be found in Exhibit 7 (see also the Department of Agriculture definition of animal in Exhibit 8).

Finally, to avoid repetition, reference is made to Applicants' voluminous comments submitted in the Preliminary Amendment dated November 2, 2004.

REJECTION OF CLAIM 16 UNDER 35USC§102

Applicants' claim 16, as amended, requires that the combination probe, transceiver and power source be non-expandable and non-compressible. This is contrary to the requirements of the Guice device (see, for example, [0179], where the curved member is defined as having a spring-like action so that the curved member can be compressed into a smaller diameter to support installation, and then expand to a larger diameter after emplacement).

Again, to avoid repetition reference is made to Applicants' comments in the Preliminary Amendment of November 2, 2004.

DEFINITION OF "IMPLANT"

With regard to the Examiner's comments on page 9 of the Office Action that the Guice probe would be capable of being removed after a period of less than 30 days, it is respectfully submitted that the FDA definition of implant (see again Exhibit 6) merely requires that a device be intended to remain there for a period of 30 days or more. Thus, the criteria is not whether or not an observer might choose to remove the Guice probe after a period of less than 30 days, but that the intention is to have the probe remain for 30 days or more.

NON-HAZARDOUS OR NON-TOXIC NATURE OF GUICE

On page 10 of the Office Action, the Examiner has indicated that the Guice probe is disclosed as being formed of materials that are "non-hazardous.....". However, it is respectively submitted that this is in reference to use of the pertaining part of the animal for food, i.e. so that such animal part can be ground up. For example, see [0158] of Guice, where it is stated that "while it is generally unacceptable for any portion of a foreign object to end up in a food product destined for humans and most pets, it may be acceptable in some cases for telesensor implants to be ground up along with the other animal processing by-products into a meat and bone meal product or similar by-product from animal product processing, so long as the materials are not toxic or otherwise harmful".

In view of the foregoing, Applicants respectfully request reconsideration of the allowability of all of pending claims 1 – 16. In addition, should the Examiner have any further comments or suggestions, the undersigned would very much appreciate

a telephone call from him in order to expedite placement of the application into condition for allowance.

Respectfully submitted,

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Attachments: Two Declarations
Exhibits 1, 2, 3, 4